



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,153	03/01/2004	Andreas Hirsch	4451.003300	9981
23720	7590	11/01/2006	EXAMINER	
WILLIAMS, MORGAN & AMERSON 10333 RICHMOND, SUITE 1100 HOUSTON, TX 77042			SAMALA, JAGADISHWAR RAO	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

78

Office Action Summary	Application No. 10/790,153	Applicant(s) HIRSCH ET AL.	
	Examiner Jagadishwar R. Samala	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9 are, drawn to a method of administering a therapeutic molecule comprising an effective amount of amphifullerene liposome comprising at least one amphifullerene, located either on the surface of liposome, between layers of liposome, entrapped within the liposome or associated with liposome, classified in class 424, subclass 9.3, 9.4, 9.5 and 9.51.
 - II. Claims 10-14 are, drawn to a amphifullerene liposome, comprising an amphiphilic fullenere, and a therapeutic agent, located either on the surface of liposome, between layers of the liposome, entrapped within the liposome, or associated with a fullerene, classified in class 424, subclass 9.3, 9.4, 9.5 and 9.51
 - III. Claims 15-16 are, drawn to a method of forming an amphifullerene liposome comprising a therapeutic agent, comprising sonicating or co-vaporizing a solution of the amphifullerence liposome and the therapeutic agent, classified in class 424, subclass 9.51

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and III are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

Art Unit: 1618

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case different inventions I and III both recite the use of therapeutic molecule comprising a amphifullerene liposome and a therapeutic agent, yet group II recites a amphifulleren liposome comprising an amphiphilic fullerene. Invention of groups I and III can be practiced by materially different product.

Inventions I (or III) and II are directed to method of forming an amphifullerene liposome comprising sonicating or co-vaporizing a solution of the therapeutic agent and administering the said therapeutic agent. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect: (2) the inventions do not overlap in scope, i.e., are mutually exclusive: and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, function. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are distinct for the reasons given above and the search required for inventions I, II and III are also different, restriction for examination purposes as indicated is proper.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly

Art Unit: 1618

and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Election of Species

1. This application contains claims directed to the following patentably distinct species.

a. A single disclosed functional group of therapeutic agent among biotin, antigen-binding moieties, tissue-recognition moieties as recited in claims 2 and 11.

b. A single disclosed species of therapeutic diagnostic molecule comprising MRI contrast agent, a CT contrast agent, an X-ray contrast agent etc as cited in claims 5 and 12,

c. A single disclosed species of forming an amphifullerene therapeutic agent comprising sonicating or co-vaporizing technique as cited in claims 15 and 16.

Applicant is required to elect a single disclosed species from each category (a), (b) and (c).

2. The species are patentably distinct because each compound has chemically different structure which may not be related or may not share same structure core.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species explicitly for prosecution, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon,

Art Unit: 1618

including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Conclusion

1. No claims are allowed at this time.
2. All pending claims are subject to restriction/election requirement.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

Art Unit: 1618

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VICKIE KIM
PRIMARY EXAMINER

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr